

DRAFT COPY FOR EXAMINER G. KISHOREIN THE CLAIMS

Amend the following claims:

1. (Currently Amended) A formulation for application to a mucosal tissue [selected from the group consisting of nasal, ophthalmic, oral cavity, gastrointestinal, respiratory, vaginal and rectal], the formulation comprising:
 - (a) a biologically active agent [selected from the group consisting of antibiotic, antiviral agent, antifungal agent, disinfectant, nutrient, anti-inflammatory agent, local anesthetic and essential oil]; and
 - (b) a lipid carrier, said lipid carrier having the property of adhesion capacity to mucosal tissue, said lipid carrier [no positively charged lipid but instead] including at least one lipid selected from the group of amphiphilic phospholipids consisting of yolk lecithin, Soya lecithin, phosphatidylglycerol and analog thereof [phosphatidylcholine, said lipid having no phospholipid envelope or a bioadhesive polymer coating,] said lipid being characterized as mixed micelles [an emulsion of lipid droplets] dispersed in an aqueous medium, and said lipid and said biologically active agent being present in a ratio [ration] of from about 10:1 to about 1:10], such that said biologically active agent is carried by said lipid of said lipid carrier and said biologically active agent is thereby released from said lipid in a sustained manner and over a prolonged period of time, such that said lipid carrier has a property of high adhesion to the mucosal tissue].

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2. (Currently Amended) The formulation of claim 1, wherein said biologically active agent is an antibiotic is selected from the group consisting of 3-de[2,6-dideoxy-3-C-methyl-3-O-methyl-.alpha.-L-ribo-hexopyranosyl]oxy]-11,12-dideoxy-6-O-methyl-3-oxo-12,11-[oxycarbonyl][4-[4-(3-pyridinyl)-1H-imidazol-1-yl]butyl]imino] [erythromycin], [4-S-(4-alpha,4a-alpha,5a-alpha,6-beta,12a-alpha)]-4-(Dimethylamino)-1,4,4a,5,5a,6-11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11 dioxo-2-naphthacenecarboxamide [tetracycline], and D-threo-N-dichloroacetyl-1-p-nitrophenyl-2-amino-1,3-propanediol; D-)-(threo-2-dichloroacetamido-1-p-nitrophenyl-1,3-propanediol [chloramphenicol].

3. (Currently Amended) The formulation of claim 1, wherein said biologically active agent is an antiviral agent is selected from the group consisting of azothymidine [azothymidin], 2-Amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-6H-purin-6-one [acyclovir], dideoxuryidine, and Cis-1-Acetyl-4-[4-[[2-(2,4-dichloro-phenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxo-1an-4-yl]methoxy]-phenyl]piperazine [amantadine].

4. (Currently Amended) The formulation of claim 1, wherein said biologically active agent is an antifungal agent is selected from the group consisting of Cis-1-Acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine [ketoconazole], 1H-1,2,4-Triazole-1-ethanol, alpha-[(2,4-difluorophenyl)-alpha-(1H-1,2,4-triazol-1-ylmethyl)-2-(2,4-Difluorophenyl)-1,3-bis(1H-1,2,4-triazol-1-yl)-2-propanol alpha-(2,4-Difluorophenyl)-alpha-(1H-1,2,4-triazol-1-ylmethyl)-1H-1,2,4-triazole-1-ethanol [flucoconazole], 1-[2,4-dichloro-beta-[(2,4-dichlorobenzyl)oxy]phenethyl]imidazole [miconazole], Methyl-(3-methylphenyl)carbamothioic acid O-2-naphthalenyl ester [tolnaftate], Polyene

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antibiotic produced by Streptomyces nodosus M4575 [amphotericin], and 2-Deoxy-4-O-(2,6-diamine-2,6-dideoxy-alpha-D-glucopyranosyl)-D-streptamine [nystatin].

5. (Currently Amended) The formulation of claim 1, wherein said biologically active agent is a disinfectant is selected from the group consisting of N,N"-Bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanedimidamide; 1,1'-hexamethylenebis[5-(p-chlorophenyl)biguanide] [chlorhexidine], chlorhexidine [chlorexidine] salts, 5-Chloro-2-(2,4-dichlorophenoxy)phenol [triclosan], centrimide, and 1-Hexadecylpyridinium chloride [cetylpyridinium chloride].

6. (Currently Amended) The formulation of claim 1, wherein said biologically active agent is a nutrient is selected from the group consisting of 3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraen-1-ol [vitamin A], [2R-2R*(4R*,8R*)]-3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol [vitamin E], (3-beta,5Z,7E,22E)-9,10-Secoergosta-5,7,10(19),22-tetraen-3-ol [vitamin D], [R-[R*,R*-(E)]1-2-Methyl-3-(3,7,11,15-tetramethyl-2-hexadecenyl)-1,4-naphthalenedione [vitamin K], (S)-(+)-2-[(R)-3,4-Dihydroxy-5-oxygen-2,5-dihydrogen-2-furan]-2-ethoxyls cetane [ascorbyl palmitate], coenzyme Q-50, 5-[3-(1,2-dithiolanyl)]pentanoic acid [lipoic], cis-tetrahydro-2-oxothieno[3,4-d]imidazoline-4-valeric acid [biotin] and 3-Carboxy-2-hydroxy-N,N,N-trimethyl-1-propanaminium inner salt; (3-carboxy-2-hydroxypropyl)trimethylammonium hydroxide, inner salt [carnitine].

7. (Original) The formulation of claim 1, wherein said biologically active agent is an anti-inflammatory agent is selected from the group consisting of non-steroidals and steroidals.

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8. (Currently Amended) The formulation of claim 7, wherein said non-steroidal anti-inflammatory agent is selected from the group consisting of 1-(4-Chlorobenzoyl)-5-methoxy-2-methyl-1H-indole-3-acetic acid [indomethacin], (RS)-2-(3-benzoylphenyl)propionic acid [ketoprofen], [o-(2,6-dichloroanilino)phenyl]acetic acid sodium salt [diclofenol], and 2-acetoxybenzoic acid [acetylsalicylic acid].

9. (Currently Amended) The formulation of claim 7, wherein said steroidal anti-inflammatory agent is selected from the group consisting of (11-beta,16-alpha) 9-Fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione [dexamethazone], (11-beta)-11,17,21-Trihydroxypregna-1,4-diene-3,20-dione [prednisolone], 21-desoxy-9alpha-fluoro-6alpha-methylprednisolone [flouromethzolone acetonide].

10. (Currently Amended) The formulation of claim 1, wherein said local anesthetic is selected from the group consisting of omega-diethylamino-2,6-dimethylacetanilide [lidocaine], trimecaine, and 4-aminobenzoic acid ethyl ester [benzocaine].

11. (Original) The formulation of claim 1, wherein said biologically active agent is an essential oil is selected from the group consisting of menthol, vanillin, peppermint oil, clove oil, eucalyptus oil and lavender oil.

12. (Previously Amended) The formulation of claim 1, wherein said biologically active agent is further characterized by having activity in the oral cavity, said activity being suitable for treatment of at least one condition selected from the group consisting of gum disease, caries, dry mouth, malodorous breath, and microbial infection.

13. (Previously Amended) The formulation of claim 12, wherein said microbial infection is selected from the group consisting of bacterial, viral, and fungal.

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14. (Previously Amended) The formulation of claim 1, wherein said biologically active agent is further characterized by having activity on a tissue from the group consisting of nasal, ophthalmic, vaginal, and rectal, said activity being suitable for treatment of at least one condition selected from the group consisting of inflammation, irritation, dryness, and microbial infection.
15. (Previously Amended) The formulation of claim 14, wherein said microbial infection is selected from the group consisting of bacterial, viral, and fungal.
16. (Previously Amended) The formulation of claim 1, wherein said lipid in (b) and said biologically active agent in (a) are present in a ratio from about 5:1 to about 1:5.
17. (Original) The formulation of claim 16, wherein said lipid and said agent are present in a ratio from about 3:1 to about 1:3.
18. (Previously Amended) The formulation of claim 1, further comprising a stabilizer, said stabilizer having at least one surfactant selected from the group consisting of non-ionic, anionic, cationic, and amphiphilic.
19. (Previously Amended) The formulation of claim 18, wherein said non-ionic surfactant is selected from the group consisting of a polyethylene glycol derivative and a glycerol derivative.
20. (Currently Amended) The formulation of claim 19, wherein said polyethylene glycol derivative is selected from the group consisting of alpha-Hydro-
omega0hydroxypoly-(oxy-1,2-ethanediyl) [Tween], Polyethylene glycol mono[4-
(1,1,3,3-tetramethylbutyl) phenyl]ether [triton], O-3-Amino-3-deoxy-D-
glucopyranosyl-(14)-O-[2,6-diamino-2,3,6-trideoxy-D-ribo-hexopyranosyl-(16)]-2-
deoxy-L-streptamine [tyloxapol], alpha-hydro-omega-

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hydroxpoly(oxyethylene)poly(oxypropylene)poly(oxyethylene) block copolymers
[pluronic], Polyethylene glycol fatty alcohol ethers [Brije], Sorbitan fatty acid esters
[Span], poloxamer, and polyethylene glycol esters of fatty acids [emulphor].

21. (Currently Amended) The formulation of claim 19, wherein said glycerol derivative is selected from the group consisting of alpha-hydro-omega-hydroxypoly(oxy-1,2-ethanediyl) [polyglycerine] and polyalkyglyceride.

22. (Previously Amended) The formulation of claim 18, where said anionic surfactant is selected from the group consisting of carboxylate, alkyl sulfonate, aryl sulfonate, and phosphate.

23. (Previously Amended) The formulation of claim 18, wherein said cationic surfactant is selected from the group consisting of alkyl pyridinium salt and tetra-alkylammonium salt.

24. (Currently Amended) The formulation of claim 18, wherein said amphiphilic surfactant is selected from the group consisting of alkyl betaine derivative, cocoamphodiacetale derivative, trimyristin, trilaurin, tripalmitin, tristearin [lauroamphoacetate], and phosphatidylglycerol.

25. (Currently Amended) The formulation of claim 1, further comprising at least one lipid additive selected from the group consisting of triglyceride, alkyl ester, cholesterol, octadecenoic acid 1,2,3-propanetriyl ester [triolein], edible oil, tetradecanoic acid 1-methyleethyl ester [medium chain glycerate isopropylmyristate], and methyl ester beta-Cholest-5-en-3-ol [cholesterol ester].

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26. (Previously Amended) The formulation of claim 1, further comprising at least one additive selected from the group consisting of flavor, aroma modifier, sweetener, color, and antioxidant.

27. (Original) The formulation of claim 1, wherein said lipid in a colloidal dispersion of as form selected from the group consisting of micelles, mixed micelles, and micellar aggregates, said lipid having a particle size of from about 10 to about 300 nm.

28. (Previously Amended) The formulation of claim 1, wherein said lipid is in the form of a dispersion having liquid particles of size in the range of from about 50 to 300 nm.

29. (Currently Amended) A method of administering a formulation to a mucosal tissue, [wherein said mucosal tissue is selected from the group consisting of nasal, ophthalmic, oral cavity, gastrointestinal, respiratory, vaginal and rectal,] comprising the steps of:

(a) providing the formulation, the formulation featuring

- (i) a biologically active agent selected from the group consisting of antibiotic, antiviral agent, antifungal agent, disinfectant, nutrient, anti-inflammatory agent, local anesthetic and essential oil; and
- (ii) a lipid carrier, said lipid carrier [having no positively charged lipid but instead] including at least one lipid selected from the group of amphiphilic phospholipids consisting of yolk lecithin, soya lecithin, phosphatidylglycerol and analogs thereof [phosphatidylcholine, said lipid having no phospholipid envelope or a bioadhesive polymer coating,] said

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lipid being characterized as mixed micelles [an emulsion of lipid droplets] dispersed in an aqueous medium, and said lipid and said biologically active agent being present in a [ration] ratio of from about 10:1 to about 1:10[, such that said biologically active agent is carried by said lipid of said lipid carrier and said biologically active agent is thereby released from said lipid in a sustained manner and over a prolonged period of time such that said lipid carrier has a property of high adhesion to the mucosal tissue]; and

(b) administering the formulation to the mucosal tissue.